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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,706	09/11/2003	Simon L. McGurk	029318-0968	4753

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
10/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,706	MCGURK ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *9-11,23,29 and 44-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12-22,24-28,30-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-17-2007 has been entered.

Claims 1 – 47 are pending and claims 9 – 11, 23, 29, and 44 – 46 are withdrawn as being drawn to non-elected subject matter. Claims 1 – 8, 12 – 22, 24 – 28, 30 – 43, and 47 are treated on the merits in this action.

Information Disclosure Statement

Applicants have submitted evidence in the form of an excerpt from the Handbook of Pharmaceutical Excipients, Fourth Edition, but have not submitted and Information Disclosure Statement listing this evidence. The document has been considered, however, Applicants response to this action should nonetheless include an Information Disclosure Statement listing the submitted document so that the consideration of the document by the office is clearly of record.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1 – 8, 12 – 22, 24 – 28, and 30 – 43 under 35 U.S.C. 102(b) as being anticipated by WO 00/1874 to Swanson is **withdrawn** in view of the factual showing that gelatin of the type used in Swanson does not inherently contain 20% to 97% water.

Claims 1 – 8, 12 – 22, 24 – 28, and30 – 43 **remain** rejected under 35 U.S.C. 102(a) as being anticipated by US 6,316,029 to Jain et al for reasons of record and those discussed below. In addition, **new claim 47** is now included in this rejection.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that although sufficient water is added to the dosage form of Jain to bring the water content within the limits of instant claim, the water is dried before the final dosage form is made (see Example 3 of Jain). Applicants continue that, based on the evidence provided, the dried gelatin is insufficiently hygroscopic to contain the recited amount of water. In response, Applicants evidence does show that the final, dry composition of Jain does not read on the instant claims. However, the intermediate composition, which is obtained after spraying with water but prior to drying (see Example 3 of Jain) anticipates the claimed composition. The fact that this anticipatory composition is an intermediate in Jain does not negate its anticipation of the claims.

Note that new claim 47 is a product by process claim, wherein the product is identical to that of claim 1. Since there is nothing of record to indicate that the process imparts any patentable distinction on the product over the prior art, this claim is also anticipated by Jain.

Claims 1 – 8, 12 – 22, 24 – 28, 30 – 43 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 719 549.

The EP reference teaches compositions of drugs dispersed in gelled agents. The drugs include famotidine (as in instant claim 24) and acetaminophen (an analgesic as in instant claims 22 and 25). Although the particle size is not discussed, based on the turbidity of the final compositins (Examples 3 – 7), the particle size is understood to be much less than 2000 nm. If the particle size were greater, higher turbidity would necessarily result. Thus the particle size limitations of instant claims 1,12, 13, 42 and 43 are met. The compositions contain two surface stabilizing agents, PEG and Poloxamer, and about 20 % water, for example, 17.06% in Example 4A, 15.6% in Example 6, and 14.68% in example 5A, among others. The concentration of the drug is between 0.001% and 99.5%, the concentration of the stabilizer is between 0.5% and 99.999%, the concentration of the gel former is between .05% and 60%, and the amount of water is from about 20% to about 95%, as required by instant claims 2 – 5, respectively. The compositions are filled in a soft gelatin shell (example 6), which results in a geometric shape, as required by instant claim 14, and are understood to include at least one of the gelatin types mentioned in claims 6 – 8. The intended use of the compositions recited in instant claims 15 – 16 is not afforded patentable weight, but nonetheless, the compositions of the art are clearly suitable for oral use (as capsules) and appear to be immediate release or fast melt release formulations. Additional excipients, as required by instant claim 17, are added in the form of sodium acetate (example 4). Al particles are either crystalline, amorphous, or a combination thereof as

required by claim 18. With regard to the solubility requirements of claims 19 – 21, all compounds will be insoluble in at least one liquid. With regard to claim 20, compounds soluble in water will not be soluble in hexane (a highly non-polar solvent), and vice versa, so all compounds will be insoluble in at least one of those two. PEG and sodium stearate are both surface stabilizers, so the second surface stabilizer required by claim 26 is present. Sodium stearate is an ionic stabilizer, as required by claim 27, and poloxamers are among the materials listed in claim 28. The properties of the composition, listed in claims 30 – 41, are understood to be inherent since the properties of a composition are inseparable from the composition itself, and since the composition of the art is the claimed composition. With regard to product by process claim 47, although these are not afforded weight since record does not indicate that the process steps impart a patentable distinction on the product, nonetheless the prior art process is the claimed process (examples 3 – 7).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615

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